Supreme Court, U.S.
FILED
JAN 9 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-614

In the Supreme Court of the United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, AND SCHUYLER LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

A regulation promulgated under the Federal Food, Drug, and Cosmetic Act provides in relevant part that a drug in a bulk package shall not be exempt from the labeling requirements of the Act if it is intended for use in the manufacture of a "new drug" unless certain requirements are met. The question presented is whether that regulation is valid as applied to bulk packages of drugs to be distributed in interstate commerce to veterinarians.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-10a) is reported at 854 F.2d 173. The opinion of the district court (Pet. App. 11a-24a) is reported at 674 F. Supp. 1344.

JURISDICTION

The judgment of the court of appeals was entered on July 27, 1988. A petition for a rehearing was denied on September 6, 1988 (Pet. App. 26a). The petition for a writ of certiorari was filed on October 12, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. To protect the food supply and the public against potentially dangerous residual effects from the use

on animals of drugs that have not been proved safe and effective, and to protect the animals themselves, the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. (& Supp. IV) 301 *et seq.*, establishes a system of premarketing approval for new animal drugs. 21 U.S.C. 360b; *Tri-Bio Laboratories, Inc.* v. *United States,* 836 F.2d 135, 138 (3d Cir. 1987), cert. denied, No. 87-1804 (Oct. 3, 1988); *United States* v. *An Article of Drug Consisting of 4,680 Pails* (*Neo-Terra*), 725 F.2d 976, 978 (5th Cir. 1984).[1] With certain exceptions not relevant here, a drug is a "new animal drug" unless it is generally recognized by qualified experts as safe and effective for the conditions prescribed, recommended, or suggested in its labeling. 21 U.S.C. 321(w)(1); *Neo-Terra,* 725 F.2d at 980. The FDCA prohibits the introduction into interstate commerce of a new animal drug unless the Food and Drug Administration (FDA) has approved a new animal drug application (NADA) for it. 21 U.S.C. 360b(a)(1)(A); *Neo-Terra,* 725 F.2d at 980. The predistribution approval requirement applies equally to prescription and over-the-counter drugs. The FDA ordinarily approves only finished drug products that are formulated and packaged for use essentially "as is" by the ultimate user, whether a practitioner or layman; approval is not granted for active bulk ingredients per se. See 21 C.F.R. 514.1(b)(4); cf. *United States* v. *Generix Drug Corp.*, 460 U.S. 453 (1983). Unapproved new animal drugs are deemed by the Act to be adulterated and are subject to seizure. 21 U.S.C. 360b(a)(1)(A), 351(a)(5), 331-334.

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[1] Section 201(g) of the FDCA defines "drugs" to include veterinary drugs. 21 U.S.C. 321(g). The Act also establishes a similar system for human drugs. 21 U.S.C. (& Supp. IV) 355; *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973).

The sponsor of a new animal drug, ordinarily a drug or animal feed company, has the burden of proving that a drug meets all criteria for approval. *United States* v. *Colahan,* 811 F.2d 287, 292 (6th Cir. 1987), cert. denied, No. 86-1783 (Oct. 5, 1987); *Rhone-Poulenc, Inc., Hess & Clark Division* v. *FDA,* 636 F.2d 750, 752 (D.C. Cir. 1980). To obtain the FDA's approval, the sponsor must prove the safety and effectiveness of the drug on the basis of scientific evidence, including adequate and well-controlled clinical studies. See, *e.g., Warner-Lambert Co.* v. *Heckler,* 787 F.2d 147, 150-151 (3d Cir. 1986). If a drug is to be used in food-producing animals, the sponsor must prove that use of the drug will not leave harmful drug residues in meat, milk, or eggs. 21 U.S.C. 360b(b)(1), (7), and (8), 360b(d) (1)(A), (B), and (H), and (d)(2). As part of the NADA approval process, the FDA determines under what conditions a drug may be used, *e.g.,* whether it may be administered only to animals that do not become a part of the food supply, and whether it may be marketed over-the-counter or must be restricted to prescription use. The conditions of use must be specified in the labeling of the drug. See, *e.g.,* 21 U.S.C. 360b(b)(6) and (d).[2]

b. Congress has required that all animal drugs marketed in interstate commerce bear "adequate directions for use." 21 U.S.C. 352(f)(1). This labeling requirement applies to all drugs, including "bulk drugs," *i.e.,* drugs intended for use as components of finished drug products. 21 U.S.C. 321(g)(1)(D). Drugs not properly labeled are "deemed to be misbranded" as a matter of law, 21 U.S.C. 352, and are subject to seizure and other regulatory action. 21 U.S.C. (& Supp. IV) 331-334.

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[2] The FDA publishes in the Code of Federal Regulations the conditions under which an approved new animal drug may be used. See 21 C.F.R. Pt. 500 *et seq.*

A proviso to 21 U.S.C. 352(f) authorizes the FDA to exempt a drug from the labeling requirement when imposition of the requirement is "not necessary for the protection of the public health." 21 U.S.C. 352(f); see *United States* v. *Ellis Research Laboratories, Inc.*, 300 F.2d 550, 552 (7th Cir.), cert. denied, 370 U.S. 918 (1962) ("Unless the [article] falls within the scope of the exemption in the regulations * * *, it is not exempt from [the] labeling requirement[]."). [3] Thus, the question of an exemption turns, in the first instance, on the FDA's scientific judgment as to whether and under what conditions adequate directions for use are unnecessary for the public health. Pet. App. 4a-5a. [4]

Because bulk drugs are not intended for use without further processing, the FDA has determined that under certain circumstances it is unnecessary for them to bear adequate directions for use. In 1952, the FDA adopted a regulation for such drugs, 21 C.F.R. 201.122 (the labeling regulation). Under that regulation, bulk drugs can be exempted from the requirement of 21 U.S.C. 352(f)(1) if they are intended for processing, repacking, or use in the manufacture of another drug, and are labeled accordingly. By its terms, however (and with certain exceptions not relevant here), the exemption does not apply to a bulk drug intended for use in a finished drug product that must itself be approved by the FDA, but does not yet have that

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[3] Although *Ellis Research Laboratories* and several other cases cited in this brief concerned medical devices, not drugs, those cases are fully applicable here, since 21 U.S.C. 352(f) imposes the same labeling requirement on drugs as on devices.

[4] The FDA has the authority to establish conditions on the grant of an exemption from the labeling requirement. See *United States* v. *El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951) (prescription drugs); *Arner Co.* v. *United States*, 142 F.2d 730, 736 (1st Cir.), cert. denied, 323 U.S. 730 (1944) (bulk drugs).

approval, *i.e.*, the finished drug product must not be an unapproved "new drug" or "new animal drug." Such a finished drug would be adulterated under the FDCA, and it could not bear adequate directions for use or qualify for an exemption from that requirement. Thus, a bulk drug supplier who wants to take advantage of the labeling exemption must identify a specific NADA approval for the use of the bulk drug and may deliver the drug only to the application holder. 21 C.F.R. 201.122(a). See also 21 C.F.R. 514.1(b)(5). The labeling regulation applies to all bulk drugs. It does not exempt bulk drugs that will be manufactured into an unapproved new animal drug by a veterinarian, and no other regulation provides such an exception.

2. a. On July 3, 1986, the United States filed this civil seizure action under the FDCA, 21 U.S.C. 334, to condemn 52 lots of bulk drugs in the possession of petitioner Schuyler Laboratories, Inc. (hereinafter petitioner). Pet. App. 2a. The drugs were being held by Schuyler for sale to veterinarians, who would compound them into finished drug products for use in treating animals.[5] The complaint alleged that all 52 lots of the bulk drugs were misbranded because they did not bear adequate directions for use, as required by 21 U.S.C. 352(f)(1).[6]

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[5] "Compounding" refers to the steps taken to prepare a finished drug product from an active ingredient. An example is the preparation of an injectable drug from an active ingredient in powder form. See 50 Fed. Reg. 27018 (1985).

[6] The complaint also alleged that five lots were adulterated since they consisted of certifiable antibiotic animal drugs that could not be marketed without the FDA's approval (21 U.S.C. 321(w)(3), 351(a)(5), 360b(n)) and because neither Schuyler nor any of its customers had obtained the requisite approval. The only issue in this respect was whether the antibiotic drugs were intended for animal use in their bulk form, because there was no dispute that the drugs had not

There was no dispute that the drugs failed to bear adequate directions for use; in fact, the drugs bore no directions at all. Pet. App. 3a, 16a. The only question involved the applicability of the FDA's labeling exemption, 21 C.F.R. 201.122, to the bulk drugs, and the validity of that regulation as applied. Schuyler claimed that the regulation was invalid as applied to the seized drugs, on the ground that it impermissibly regulated the practice of veterinary medicine.

b. The district court granted Schuyler's motion for summary judgment. Pet. App. 14a-24a. The court held that the drugs were not misbranded since, in the court's view, the regulation was invalid insofar as the denial of an exemption applied to the distribution of a bulk drug to a veterinarian. *Id.* at 19a-23a. The court held that portion of the regulation invalid as applied on the ground that the FDA cannot require that drugs compounded by veterinarians be subject to approval by the agency. *Id.* at 19a-20a, 22a-23a.

c. The court of appeals reversed. Pet. App. 1a-10a. It ruled that the labeling regulation did not improperly interfere with the practice of veterinary medicine. *Id.* at 5a-8a. Although the FDCA contemplated that States would continue to determine whether a medical practitioner "had selected wisely from among methods of treatment," "[n]othing in the history or structure of the Act permits drugs deemed ineffective or dangerous by the FDA to be

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received FDA approval. Congress has since deleted 21 U.S.C. 321(w)(3) from the FDCA, however, see the Generic Animal Drug and Patent Term Restoration Act, § 107(a)(1), Pub. L. No. 100-670 (Nov. 16, 1988), and this allegation is not in issue.

available for use." *Ibid.* (citing *United States* v. *Rutherford,* 442 U.S. 544 (1979)). That distinction was sensible, the court explained, because "no individual veterinarian will possess complete knowledge of the efficacy of a novel drug compound—let alone of its persistence in the food chain." *Id.* at 6a. The court also rejected petitioner's claim that, because veterinarians are exempt from the registration and inspection provisions of the FDCA when they compound medicines, the FDA's labeling regulation unlawfully intrudes into their medical practice. That argument, the court explained, rests on the erroneous assumption that a veterinarian is entitled to obtain any drug, even one not approved by the FDA. The limited exemption of practitioners from certain provisions of the FDCA does not entitle a veterinarian to obtain and use adulterated or mislabeled drugs. *Id.* at 7a.[7]

ARGUMENT

Petitioner claims that FDA's labeling regulation improperly interferes with the practice of veterinary medicine by depriving veterinarians of drugs they believe necessary to treat diseases in animals. The court of appeals correctly rejected that claim. The FDA's labeling regulation is consistent with the text and structure of the FDCA, and it serves the Act's public health goals by channeling bulk

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[7] The district court also found that the regulation was unreasonable because it placed on the distributor of bulk drugs what the court believed was an "impossible" burden of proving that bulk drugs will be used in a lawful manner by its customers. Pet. App. 21a-22a. The court of appeals rejected that conclusion, since a drug supplier can simply ask the recipient whether it possesses an approved NADA and can also examine the list of approvals published in the Federal Register. See page 3 note 2, *supra.* Petitioner has not renewed in this Court its claim that it is impossible to comply with the regulation.

animal drugs to uses in finished drugs that have been demonstrated to be safe and effective. Petitioner's interpretation of the FDCA, by contrast, would permit a drug manufacturer to market all drugs, including prescription drugs, outside the Act's elaborate approval mechanism. That result would turn on its head the system adopted by Congress to protect the public against the effect of unapproved new animal drugs on the food supply, and to protect the animals themselves. Accordingly, because the decision below is correct and does not conflict with any decision of this Court or of any other court of appeals, review by this Court is not warranted.

1. Congress has authorized the FDA to promulgate regulations exempting drugs from the requirement that labeling bear "adequate directions for use" if the agency finds that the requirement is "not necessary for the protection of the public health." 21 U.S.C. 352(f). Since that provision is "an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation," the FDA's regulation cannot be set aside unless it is "arbitrary, capricious, or manifestly contrary to the statute." *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 843-844 (1984) (footnote omitted). The agency's labeling regulation easily passes that test.

a. The FDCA establishes a comprehensive mechanism regulating the distribution of animal drugs to ensure that finished new animal drug products not demonstrated to be safe and effective will not be administered. Thus, a new animal drug cannot be marketed unless it is approved by the FDA, and to obtain the FDA's approval a drug manufacturer must prove, on the basis of adequate and well-controlled studies by qualified experts, that the drug is safe and effective for all uses recommended or suggested in the labeling, and that it will not cause harmful residues in meat, milk, or eggs. Pages 1-3, *supra*.

The FDA's labeling regulation plays an integral role in that process. It ensures that distributors like petitioner cannot circumvent the approval requirement by distributing bulk drugs to third parties who will thereafter create unapproved new drug products. See *DeFreese* v. *United States,* 270 F.2d 730, 736 (5th Cir. 1959), cert. denied, 362 U.S. 944 (1960) (bulk prescription drugs are not exempt from the labeling requirements of 21 U.S.C. 353(b) if the FDA has not exempted them). Cf. *United States* v. *Rutherford,* 442 U.S. at 551-559. Moreover, nothing in the legislative history of the Act suggests that a drug manufacturer or distributor may distribute misbranded or adulterated bulk drugs, or drugs that are deemed dangerous or ineffective by the FDA, simply because the recipient is a veterinarian.

b. Petitioner argues (Pet. 12-15) that Congress has implicitly exempted veterinarians (and therefore those who manufacture and distribute drugs destined for them) from the premarketing approval requirement, because Congress has exempted veterinarians and other medical practitioners from the registration and inspection provisions of the FDCA. 21 U.S.C. 360(g)(2), 374(a)(1)(B). As the court of appeals explained (Pet. App. 7a-8a), however, those limited exemptions have no application here. Veterinarians may use and compound, without registration, only those drug ingredients they may lawfully acquire, and they may not lawfully acquire misbranded bulk animal drugs. The registration and inspection exemptions do not justify the distribution and compounding of drugs when doing so violates other provisions of the FDCA. In fact, one of the reasons why Congress allowed practitioners to compound finished drug products is that the FDCA forbids drug manufacturers and distributors from marketing adulterated or misbranded components of finished drug products. The interpretation of the Act adopted by the court of

appeals therefore gives effect to both those limited exemptions and the premarketing approval provisions of the FDCA.[8]

There is no justification for creating an implicit exception to the requirements of the FDCA for the distribution of bulk animal drugs to veterinarians. Contrary to the assertions of petitioner and amici, the fact that veterinarians exercise professional judgment in treating animals is not a sufficient basis for inferring that Congress has exempted them from the limitations otherwise applicable to the distribution of new animal drugs. In fact, in 1962, when it added the efficacy requirement to the premarketing approval process, Congress concluded that the determination whether a drug is effective cannot rest on the knowledge and experience of individual physicians. As this Court noted in *Hynson,* "[t]he hearings underlying that 1962 Act show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous." 412 U.S. at 619 (footnote omitted). See also *Warner-Lambert Co.,* 787 F.2d at 156 (in the 1962 amendments Congress rejected the notion "that individual physicians should be left to decide whether particular drugs were effective"). Instead of leaving to the judgment of individual practitioners what new drugs may be distributed, Congress has established an elaborate approval process for new human and animal drugs and prohibited the distribution of such drugs unless they have been proved safe and effective. Drug manufacturers and distributors are

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[8] As the court below stated (Pet. App. 9a): "The effect of § 352(f) and § 201.122 is that ingredients that can be used to produce 'new' drugs may be sold only to firms that hold approved (or have filed) new animal drug applications. The FDA carefully scrutinizes the activities of these manufacturers. This is a sensible result in light of the structure of the statute."

not exempt from that process when they distribute new animal drugs to veterinarians.

There is also no merit to petitioner's argument (Pet. 10-11) that restricting the drugs veterinarians can receive improperly interferes with the practice of veterinary medicine. As the court of appeals explained (Pet. App. 5a), the FDA may legitimately restrict the sale of drugs to or by practitioners pursuant to its statutory authority to prohibit the distribution of new human or animal drugs that have not been proved to be safe and effective. For example, in *United States* v. *Rutherford, supra,* this Court held that the FDCA does not permit physicians to obtain laetrile for use in terminally ill cancer patients without the FDA's prior approval of that drug.[9] See also *United States* v. *Evers,* 643 F.2d 1043, 1048 (5th Cir. 1981) (stating that the FDCA was plainly intended to control the availability of drugs for prescription or use by practitioners); *United States* v. *Articles of Drug,* 625 F.2d 665, 675 (5th Cir. 1980); *Rutherford* v. *American Medical Ass'n,* 379 F.2d 641, 643 (7th Cir. 1967), cert. denied, 389 U.S. 1043 (1968) (rejecting a request by a physician and his patients for an injunction against the FDA and others from interfering with the distribution of an unapproved cancer-treatment drug); cf. *Pharmaceutical Mfrs. Ass'n* v. *FDA,* 484 F. Supp. 1179, 1188 (D. Del.), aff'd, 634 F.2d 106 (3d Cir. 1980) ("The fact that the practice of medicine is an area traditionally regulated by the states does not invalidate those provisions of the Act which may at times impinge on some aspect of a doctor's practice."). For years the FDA,

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[9] Although the Court did not discuss whether the laetrile was in finished or bulk form, the difference is inconsequential. As the *Rutherford* Court stated with respect to other unapproved remedies for terminal patients, if the ruling had been limited to finished drugs, the market for bulk laetrile would not long have been overlooked by inventive minds. See 442 U.S. at 557-558.

under statutory authority, has required prescription drugs to be subject to the new drug approval process,[10] and virtually all major prescription drugs used or prescribed by practitioners have been approved by FDA. See, *e.g.*, 47 Fed. Reg. 46625 (1982). If petitioner were correct, the FDA's approval system for both human and animal drugs would be an unlawful infringement on the practice of medicine. No case supports such a proposition, and the authority is to the contrary. See *United States* v. *Ellis Research Laboratories, Inc.*, 300 F.2d 550, 552-553 (7th Cir.), cert. denied, 370 U.S. 918 (1962) (holding that licensed practitioners are not per se exempt from the adequate directions for use provisions of the FDCA).

The agency's construction of the FDCA is fully consistent with its underlying purpose of protecting the public health. See *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The unrestricted distribution of bulk drugs would expose the public to the risk of harmful residues in food, since none of the finished

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[10] When Congress required the approval of new drugs and new animal drugs under 21 U.S.C. 355 and 360b, it contemplated that the FDA would have authority to approve prescription as well as over-the-counter drugs. For example, 21 U.S.C. 353(b), which establishes the criteria for the dispensing of human drugs, explicitly refers to prescription drugs that must otherwise be labeled as required by 21 U.S.C. 352(f). See 21 C.F.R. 201.105(c)(2); *United States* v. *Colahan*, 635 F.2d 564 (6th Cir. 1980), cert. denied, 454 U.S. 831 (1981). Congress has recently codified the requirements for veterinary prescription drugs. See the Generic Animal Drug and Patent Term Restoration Act, § 105, Pub. L. 100-670. The FDA has approved a large number of animal drugs that are so restricted, as shown in the approval regulations that are published in 21 C.F.R. Pt. 520 *et seq.* The drugs are approved in finished form and are subject to detailed labeling and other requirements, including labeled directions and conditions for use. 21 C.F.R. 201.105. Section 201.100 has similar labeling requirements for human prescription drugs.

animal drug products compounded by veterinarians will have been subjected to the stringent testing requirements set forth in the Act to determine what (if any) residues occur in edible food products. For example, during the approval process for a new animal drug that is to be used in food animals, the FDA establishes the withdrawal time[11] based on studies done with the finished drug product that will be marketed if the FDA approves the NADA. An approved drug product is formulated and manufactured in a particular way; it contains specified inactive ingredients, as well as an active ingredient obtained from a particular source; and it is manufactured under specified conditions. See, *e.g.*, 21 C.F.R. 514.1 (b)(4)-(7). Differences in any of those factors, especially in the choice of inactive ingredients, can significantly affect the amount and kind of drug residue that occurs in the food the public consumes.[12] It is for such reasons that the FDCA requires that each individual drug product be tested to determine whether it is safe as well as effective in its finished form.

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[11] The withdrawal time is the length of time prior to slaughter (or marketing of milk or eggs) for which use of the drug is to be discontinued in order to ensure that no harmful residue will occur in edible products.

[12] See 21 C.F.R. 514.1(b)(4)-(8); 50 Fed. Reg. 27016 (1985); *Generix*, 460 U.S. at 455-456; *United States* v. *Undetermined Quantities of Various Articles of Drugs* * * * *Equidantin Nitrofurantoin Suspension*, 675 F.2d 994, 1001 (8th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *United States* v. *Premo Pharmaceutical Laboratories, Inc.*, 511 F. Supp. 958, 963-965 (D.N.J. 1981). These cases explain how differences in a drug's actions can be caused by differences in ingredients and formulations. The tragedies that can result from the use of drugs that are similar to approved drugs, but are not themselves approved, and from the use of seemingly innocuous but unapproved inactive ingredients, are explained in *Pharmadyne Laboratories, Inc.* v. *Kennedy*, 466 F. Supp. 100, 105-106 (D.N.J.), aff'd, 596 F.2d 568 (3d Cir. 1979), and *Equidantin*, 675 F.2d at 998.

Petitioner's interpretation of the statutory scheme, by contrast, would expose the public to serious health risks. Under the procedure advocated by petitioner, each veterinarian would be free to use any inactive ingredient he chooses, to compound any drug in any manner he wishes, and to establish his own withdrawal times, if any. As the court of appeals recognized, "no individual veterinarian will possess complete knowledge of the efficacy of a novel drug compound—let alone of its persistence in the food chain." Pet. App. 6a. This case illustrates the nature of those risks. Several of the drugs that are the subject of this action fall into categories found to cause cancer in test animals. *Ibid.* Those drugs, accordingly, present a risk of cancer to humans if residues are found in food.[13]

Petitioner asserts (Pet. 6-7) that veterinarians need bulk drugs to treat otherwise untreated diseases. That is a policy question for Congress and the FDA to decide. Moreover, petitioner's claim is undercut by its admission (Pet. 2) that many of the drugs seized in this case are "common, well-known products," thus suggesting that the motivation for the use of many bulk drugs may be economic, not therapeutic.

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[13] The FDA has withdrawn existing approvals for finished drugs that contain dimetridazole, 52 Fed. Reg. 25312 (1987), and has proposed to withdraw approvals for finished nitrofuran products (including nitrofurazone) because of the risk of residue in food. 49 Fed. Reg. 34965 (1984). Further, one of the sulfonamides (sulfas) has recently been found to cause cancer in test animals, 53 Fed. Reg. 15886 (1988), and illegal residues of sulfas have been found on a continuing basis in swine. See 50 Fed. Reg. 20796 (1985). See also 21 C.F.R. 510.450(a)(1) (concerning residues of sulfas).

The FDA has also found that drugs in another category among those that were the subject of this action—antibiotics—are new animal drugs, since those drugs are particularly capable of causing injurious drug residues in meat, milk, and eggs. See 21 C.F.R. 510.110; *Rhone-Poulenc*, 636 F.2d at 750 (an example of the harmful residue that can occur in human food as a result of animal drug use).

Finally, petitioner argues (Pet. 16-18) that the decision below is inconsistent with the Virus-Serum-Toxin Act (VSTA), 21 U.S.C. (& Supp. IV) 151-159. Petitioner did not raise that claim below, but it lacks merit in any event. The VSTA is an entirely separate law and supplies no assistance in interpreting the provisions of the FDCA. If anything, that Act supports the court of appeals' decision. The VSTA exempts biologics prepared by veterinarians from the Act's premarketing approval requirements by exempting such products from the licensing provisions that apply to other biologics. 21 U.S.C. (Supp. IV) 154a. That provision shows that Congress knows how to exempt veterinarians from premarketing approval requirements when it wishes to do so, and it has not done so in the case of bulk animal drugs.

c. The FDA's construction of the FDCA is entitled to deference. The labeling regulation was adopted in 1952, and the agency has for many years construed the Act to prohibit the distribution of a bulk drug that is used to create an unapproved new animal drug. See FDA *Compliance Policy Guide* § 7125.10 (July 13, 1976), *quoted at* Pet. App. 7a ("[V]eterinarians may use in the compounding of prescriptions for their private practice whatever bulk drugs or other pharmaceuticals *they may lawfully purchase*.") (emphasis added).[14] Neither the labeling regulation nor any other in the intervening years has made

[14] Since 1952, the FDA's bulk drug exempting regulation has contained a condition that the finished drug product not be an unapproved "new drug." 21 C.F.R. 1.106(l) (promulgated July 25, 1952, 17 Fed. Reg. 6818). The FDA has regulated bulk drugs for many years (see, *e.g.*, *Arner Co.* v. *United States*, 142 F.2d 730, 734-736 (1st Cir.), cert. denied, 323 U.S. 730 (1944)), including bulk drugs intended for use by veterinarians. See, *e.g.*, *United States* v. *Articles of Drug* * * * *17 1200-Gram Drugs* * * * *Sulfachlorpyridazine*, Civ. No. F74155 (E.D. Cal. Feb. 9, 1977); FDA *Compliance Policy Guide* § 7125.10, which has been in effect at least since 1976.

an exception for drugs sold to practitioners. Moreover, deference is particularly appropriate here, since the Act delegates authority to the FDA to protect the public health, and the FDA's judgment whether labeling is necessary for that purpose is "within its area of special expertise, at the frontiers of science." *Baltimore Gas & Elec. Co.* v. *NRDC*, 462 U.S. 87, 103 (1983). See also *Young* v. *Community Nutrition Inst.*, 476 U.S. 974, 981 (1986).

In sum, petitioner's construction of the Act not only would risk contamination of the food supply but also would undermine the FDA's entire system for regulating bulk drugs, regardless of whether the drugs are intended for use in the manufacture of human or veterinary drugs, or whether the finished products are intended for prescription or over-the-counter use. Section 201.122 applies in each circumstance. The FDA has properly exercised its authority to regulate bulk drugs early in the distribution chain in order to minimize the risk that consumers will be exposed to adulterated and misbranded finished drug products.

2. There is no conflict among the circuits on the question presented by this case. No other court of appeals has considered whether the labeling exemption in 21 C.F.R. 201.122 is within the FDA's statutory authority, and only one other district court has considered that issue. *United States* v. *Algon Chemical Inc.*, 689 F. Supp. 394 (D.N.J. 1988), appeal pending, No. 88-5478 (3d Cir. Jan. 9, 1989), *reprinted at* Pet. App. 34a-44a. The district court in that case relied on the district court's decision in this case (Pet. App. 41a-43a), which was reversed by the court of appeals. A conflict between a court of appeals and a district court, however, does not warrant review by this Court.

There is no conflict between the other decisions cited by petitioner (Pet. 19-22) and the court of appeals' decision in

this case. For example, petitioner errs in relying on excerpts from *Chaney* v. *Heckler*, 718 F.2d 1174, 1179-1182 (D.C. Cir. 1983), rev'd on other grounds, 470 U.S. 821 (1985). That case involved the use by physicians of drugs that had been *approved* by the FDA for certain uses but not for the specific use—the administration of lethal injections to condemned prisoners. By contrast, this case involves the use of *unapproved* drugs. Moreover, the court of appeals held in that case that the FDA had the authority to limit the uses that a physician could make of an approved drug. 718 F.2d at 1179-1182. *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981), also relied on by petitioner, held that a physician did not violate 21 U.S.C. 352(f) and 21 C.F.R. 201.5 by distributing a drug to his patients. But the case is not on point because the court there expressly held that, since the drug was a prescription drug prescribed and dispensed by a licensed physician, it was exempted from 21 U.S.C. 352(f)(1) under provisions not relevant here. 643 F.2d at 1051, 1053. Finally, *Pharmaceutical Mfrs. Ass'n* v. *FDA*, *supra*, actually supports the judgment below: it upheld an FDA regulation, promulgated in part to enforce the labeling provisions of 21 U.S.C. 352(a) and (f), that required physicians and pharmacists to supply patients with certain information when drugs containing estrogen were prescribed for them. The court expressly rejected the claim that the regulation interfered with the practice of medicine. 484 F. Supp. at 1184-1185.[15]

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[15] *Grinspoon* v. *DEA*, 828 F.2d 881 (1st Cir. 1987), cited by petitioner (Pet. 21-22), is not remotely relevant. The question there involved the meaning of a statutory requirement for classifying a substance as a Schedule I narcotic under the Controlled Substances Act, 21 U.S.C. 811-812. The court held that the fact that the FDA has not approved a substance does not automatically render it a controlled substance, since the FDA may not approve a substance for reasons having nothing to do with its medical use. 828 F.2d at 887.

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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JANUARY 1989

U.S. GOVERNMENT PRINTING OFFICE 1989—241 699 00053